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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,343	07/05/2005	Raymond Ming Wah Chau	2001-103US	8965

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EXAMINER	
AUDET, MAURY A	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 04/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/541,343	CHAU ET AL.	
	Examiner	Art Unit	
	Maury Audet	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 July 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-22* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

It is noted at the outset that claims 29-31 have been misnumbered, and that these claims actually constitute claims 20-22. Applicant is asked to correct this in response to the present action. Claims 1-22 (not 1-31) are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-7 and 10, drawn to motoneuronotrophic factor peptide analogues of 6 to 32 amino acids, comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 2 or 3, or composition thereof.

II. Claim 8, drawn to a conjugate comprising a motoneuronotrophic factor peptide analogues of 6 to 32 amino acids, comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 2 or 3 and a carrier protein linked thereto.

III. Claim 8, drawn to a conjugate comprising a motoneuronotrophic factor peptide analogues of 6 to 32 amino acids, comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 2 or 3 and a solid particle linked thereto.

IV. Claim 8, drawn to a conjugate comprising a motoneuronotrophic factor peptide analogues of 6 to 32 amino acids, comprising an amino acid sequence selected from the group consisting of

SEQ ID NO: 2 or 3 and a label linked thereto.

V. Claim 9, drawn to a fusion protein comprising a motoneuronotrophic factor peptide analogues of 6 to 32 amino acids, comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 2 or 3 and a heterologous protein fused thereto.

VI. Claim 11, drawn to a composition for selectively promoting motor neuron viability and axon regeneration comprising an effective amount of a motoneuronotrophic factor peptide analogue of 6 to 32 amino acids, comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 2 or 3.

VII. Claim 12, drawn to a composition for use in targeting muscle reinnervation comprising an effective amount of a motoneuronotrophic factor peptide analogue of 6 to 32 amino acids, comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 2 or 3.

VIII. Claim 13, drawn to a composition for use in treating peripheral nerve injuries comprising an effective amount of a motoneuronotrophic factor peptide analogue of 6 to 32 amino acids, comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 2 or 3.

IX. Claim 14, drawn to a composition for use in treating neurodegenerative disease comprising an effective amount of a motoneuronotrophic factor peptide analogue of 6 to 32 amino acids, comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 2 or 3.

X. Claim 15, drawn to a composition for use in wound healing comprising an effective amount of a motoneuronotrophic factor peptide analogue of 6 to 32 amino acids, comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 2 or 3.

XI. Claim 16, drawn to a method for selectively promoting motor neuron viability and axon

regeneration comprising an effective amount of a motoneuronotrophic factor peptide analogue of 6 to 32 amino acids, comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 2 or 3.

XII. Claim 17, drawn to a method of reducing apoptosis of damaged motoneurons ans associated Schwann cells comprising an effective amount of a motoneuronotrophic factor peptide analogue of 6 to 32 amino acids, comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 2 or 3.

XIII. Claim 18, drawn to a method of inhibiting the growth, viability or migration of non-neuronal cells selected from the group consisting of fibroblasts, macrophages and lymphocytes comprising an effective amount of a motoneuronotrophic factor peptide analogue of 6 to 32 amino acids, comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 2 or 3.

XIV. Claim 19, drawn to a method of treating a spinal cord injury comprising an effective amount of a motoneuronotrophic factor peptide analogue of 6 to 32 amino acids, comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 2 or 3.

XV. Claim 20, drawn to a method of treating neuromuscular degenerative diseases where muscles associated with diseased motoneurons degenerate comprising an effective amount of a motoneuronotrophic factor peptide analogue of 6 to 32 amino acids, comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 2 or 3.

XVI. Claim 21, drawn to a method of protecting motoneurons from degeneration comprising an effective amount of a motoneuronotrophic factor peptide analogue of 6 to 32 amino acids, comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 2 or 3.

XVII. Claim 22, drawn to a method of alleviating peripheral neuropathy and neuropathic pain comprising an effective amount of a motoneuronotrophic factor peptide analogue of 6 to 32 amino acids, comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 2 or 3.

An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: (1) a product and a process specially adapted for the manufacture of said product; or (2) a product and a process of use of said product; or (3) a product, a process specially adapted for the manufacture of the said product, and a use of the said product; or (4) a process and an apparatus or means specifically designed for carrying out the said process; or (5) a product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process. If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c).

Peptide Markush Group-Lack of Unity

The invention independently drawn to to a markush group of distinct peptides (see claims 14-15). For the members of a Markush group to have unity of invention, *all* members must have a common core structure or be a member of an art recognized class. Neither of the above applies to the peptides of the present invention (see e.g. SEQ ID NO: 2 verus SEQ ID NO: 3, no core structure therebetween). Thus, the Markush groups lack unity of invention. (See Annex B to PCT Administrative Instructions, P. A1-59).

Requirement for Peptide, Conjugate, or Fusion Protein Election

As described above, the peptides comprising SEQ ID NO: 2 versus SEQ ID NO: 3, directed to any of Groups I-XVII, do not contain a substantial, distinguishable core structure/sequence that runs through them respectively. Thus an individual sequence and/or structure search is required of each compound of the invention. However, it is noted that SEQ ID NO: 2 is present in it's entirety in each of SEQ ID NOS: 1 and 4-7. Whereas SEQ ID NO: 3, although present in it's entirety in SEQ ID NOS: 1, and 6-7, is only partially present in SEQ ID NOS: 4 and 5. Thus, the Examiner is willing to separate the peptides of the invention in 2 groups:

1. SEQ ID NO: 2 (and thus a search of SEQ ID NOS 1, and 4-7); or
2. SEQ ID NO: 3 (and thus a search of SEQ ID NOS: 1, and 6-7).

Therefore, if any of Groups I-XVII is the elected invention, and irrespective of which Group is the elected invention, Applicant is required elect either SEQ ID NO: 2 or 3 (and it's respective parenthetical coextensively searchable sequences), to which the invention will be examined on the merits as drawn to.

Additionally, should Applicant elect the conjugate of Group III comprising a solid particle conjugated to a peptide comprising SEQ ID NO: 2 or 3, or elect the conjugate of Group IV comprising a label linked to a peptide comprising SEQ ID NO: 2 or 3; Applicant is required to elect, as the invention, the specific solid particle or label to be conjugated thereto, respectively. The basis for this requirement is that any conjugate thereto constitutes a separate and distinct invention, not coextensively searchable, since a solid particle or label is not necessarily a peptide (e.g. a carrier protein, the other contemplated material to be conjugated),

which would necessarily be found in an open database search any conjugate peptide comprising as part of the peptide, SEQ ID NO: 2 or 3.

However, should either SEQ ID NO: 2 or 3 be found to be novel, irrespective of which peptide of SEQ ID NO: 2 or 3 is elected as the peptide of the invention, AND any of Groups II-IV be elected as the invention; the Examiner is willing to rejoin Groups II-IV into a single Group. This is on the basis that any peptide or non-peptide (e.g. solid particle or label) conjugated to a peptide comprising SEQ ID NO: 2 or 3, would necessarily be novel as well.

Likewise, should Group I be elected as the invention, the Examiner is also willing to rejoin all of Groups II-V, with Group I, should either SEQ ID NO: 2 or 3 be found to be novel, irrespective of which peptide of SEQ ID NO: 2 or 3 is elected as the peptide of the invention. Again, this is on the basis that any peptide or non-peptide (e.g. solid particle or label) conjugated to a peptide comprising SEQ ID NO: 2 or 3, would necessarily be novel as well.

This requirement is not to be taken as an election of species, but rather as an election of a single invention, since each compound is assumed to be a patentably distinct invention, in the absence of evidence to the contrary.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CRF 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 04/15/2006

MAURY AUDET
PATENT EXAMINER
ART UNIT 1654